MISSOURI BOARD OF PHARMACY
NEWSLETTER

MAY 2018

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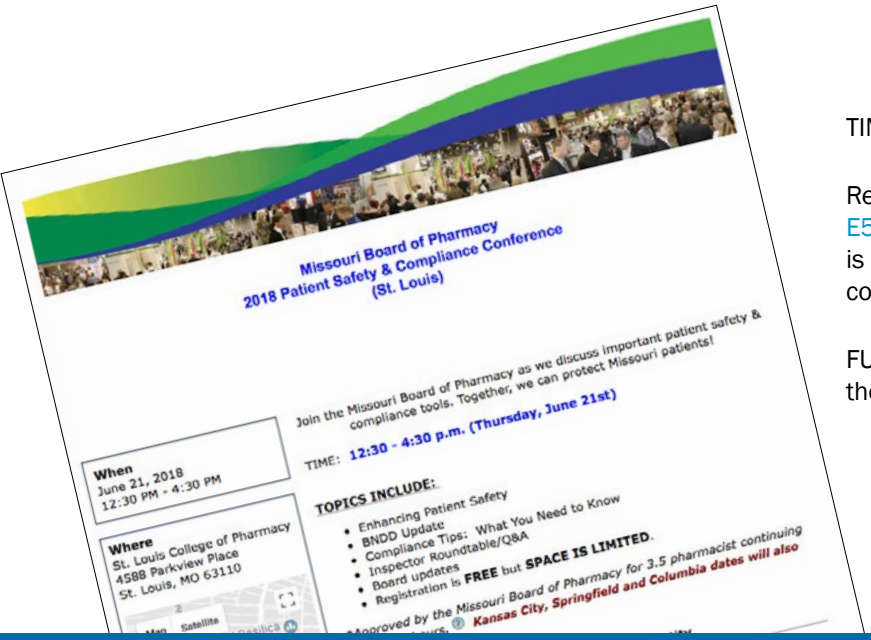
LICENSING NOTES

- All pharmacy technician registrations must be renewed by May 31st. Technicians who do not renew by May 31st are not eligible to work. Visit the Board's website to make sure all technician registrations are current and active.
- Pharmacist renewals will be mailed in August. Pharmacist licenses must be renewed by October 31, 2018. Avoid delays and update your address on the Board's website today. Remember, pharmacists need 30 hours (3.0 CEU) of approved continuing education (CE) in order to renew (20 CSR 2220-7.080). For the 2018 renewal, CE must be completed between November 1, 2016 and October 31, 2018, to be eligible.
- See pg. 2 for Pharmacist CE Guide



COMING TO A CITY NEAR YOU!

MISSOURI BOARD OF PHARMACY 2018 PATIENT SAFETY & COMPLIANCE SEMINAR

WHERE: St. Louis College of Pharmacy

- 4588 Parkview Place
  St. Louis, MO 63110

DATE: June 21, 2018 (St. Louis)

TOPICS:

- Enhancing Patient Safety
- BNDD Update
- Compliance: What You Need to Know
- Inspector Roundtable/Q&A
- Board Updates

TIME: 12:30 p.m. to 4:30 p.m.

Register online at http://www.planetReg.com/E59143826229857. Registration is FREE but space is limited. Board approved for 3.5 Missouri pharmacist continuing education hours.

FUTURE DATES: (Registration will be opened 30 days before the meeting)

August 14, 2018 (Springfield)

September 13, 2018 (Kansas City)

October 23, 2018 (Columbia)

PHARMACIST CE GUIDE

Who?	Number of hours required	CE DATE RANGE (Your CE must be earned in this date range)	Can I use it as part of my 30 hours?	Notes
All Missouri licensed pharmacists (In-state & out-of-state) [20 CSR 2220-7.080]	30	11/1 - 10/31 of EVEN numbered years (e.g., Nov. 1 2016 - Oct. 31, 2018; Nov. 1, 2018 - Oct. 31, 2020, etc.)	Yes	
Pharmacists dispensing/providing patient counseling on blood clotting factor concentrates [20 CSR 2220 - 6.100(3)]	4 hours of approved CE related to blood clotting factor concentrates, infusion treatment or therapy or blood clotting disorders or diseases	11/1 - 10/31 of even numbered years (e.g., Nov. 1 2016 – Oct. 31, 2018; Nov 1. 2018- Oct. 31, 2020 etc.)	Yes	The CE requirement only applies to certain pharmacists dispensing blood clotting factor concentrates and pharmacists who provide patient counseling regarding blood-clotting factor concentrates to bleeding disorder patients. See 20 CSR 2220-6.100(3) for definitions of "blood-clotting product" and a "bleeding disorder patient" and for more information on who needs to comply.
Pharmacist Administering by Prescription Order [20 CSR 2220-6.040(3)	2 hours of approved CE related to administering drugs/vaccines	Must have been completed within the calendar year prior to submitting your NOI.	Yes	The same two hours of CE may be used for pharmacists submitting both a Notice of Intent to Administer Medication by Prescription Order and a Notice of Intent to Administer Vaccines by Protocol.
Pharmacist Immunizing by Protocol [20 CSR 2220-6.050(3)	2 hours of approved CE related to administering vaccines	Must have been completed within the calendar year prior to submitting your NOI.	Yes	See note above
Pharmacists with a Certificate of Medication Therapeutic Services ("MTS Certificate) [20 CSR 2220-6.070]	6 hours of approved CE related to medication therapy management	11/1 - 10/31 of even numbered years (e.g., Nov. 1 2016 – Oct. 31, 2018; Nov 1. 2018- Oct. 31, 2020, etc.)	Yes	The Board will accept approved MTS CE related to any drug therapy or disease state management. These courses generally have an "01" Drug Therapy Related ACPE universal activity number (Example: ACPE Universal Activity Number: xxxx-xxxx-xx-xxx-x01-x).
Intern Pharmacists/ Pharmacy Technicians	NO CE REQUIREMENTS	NO CE REQUIREMENTS	N/A	

INSPECTION TIP: COMPOUNDING COMMERCIALLY-AVAILABLE PRODUCTS

As new FDA-approved products are introduced into the market, pharmacists must continually evaluate what is commercially-available in order to determine what can be compounded for patients. Some recent examples include:

Brand Name	Generic Name	Dosage Form
Firvanq	Vancomycin HCl	Oral Solution
CaroSpir	Spironolactone	Oral Suspension
Epaned	Enalapril Maleate	Oral Solution
Qbrelis	Lisinopril	Oral Solution
Xatmep	Methotrexate	Oral Solution
Endometrin	Progesterone	Vaginal Insert

20 CSR 2220-2.400 prohibits the compounding of a commercially-available product unless there is sufficient documentation of a specific medical need for it to be compounded. The "specific medical need" is the medical reason why the commercially available product cannot be used. Cost or convenience are insufficient reasons.

Alternatively, a pharmacist may compound a commercially-available product if it is unavailable from their suppliers due to a drug or supply shortage. Pharmacists should document the unavailability on the prescription or compound log. Pharmacists must stop compounding the product once the commercially-available product returns to the market.

The Board does not consider compounding kits that include compounding ingredients to be commercially-available products so a pharmacist may still compound these preparations without using the kit. When compounding using a kit, the pharmacist must still complete a compound log and label the patient container with the names of the active ingredients.

The Board does not consider the reconstitution of a FDA-approved product as compounding.

SHINGLES VACCINES

With the addition of Shingrix (Zoster Vaccine Recombinant, Adjuvanted) as another option for shingles immunizations, pharmacists should review their protocol to ensure it gives them the authority to immunize with Shingrix since it differs from Zostavax which is a live vaccine. Shingrix also differs from Zostavax by being a two-dose series, having a different age recommendation, and having a different dosage and administration route. Pharmacists providing Shingrix by medical prescription order should review their existing policies and procedures and make any necessary amendments to encompass these differences.

TRANSFER OF CONTROLLED SUBSTANCE PRESCRIPTION INFORMATION FOR INITIAL DISPENSING

The Board continues to receive questions on when an unfilled new controlled substance prescription may be transferred from one pharmacy to another pharmacy for initial dispensing. The information below is our understanding of current DEA guidance as it relates to DEA-registered retail pharmacies.

Type of prescription	May be transferred	May be forwarded
Written	No	No
Faxed	No	No
Verbal	No	No
Electronic (EPCS)	No	Yes**

**DEA has informed us that the forwarding of an electronic prescription may only be accomplished by using an EPCS compliant system.

DEA regulation 21 CFR 1306.27 allows for the provision of prescription information between retail pharmacies and central fill pharmacies. Please review this regulation if a central fill pharmacy is involved.

UPCOMING 2018 BOARD MEETING DATES

DISCIPLINARY ACTIONS

PHARMACISTS:

Loan K. Blinne, #043197, Winfield, MO. Probation for three (3) years. As Pharmacist-in-Charge, removed controlled substances from pharmacy to store at an unregistered location. Filed false insurance claims, failed to maintain records, and reused prescription vials. Practiced while suspended for failure to file/pay Missouri taxes. Section 338.055.2(4), (5), (6), (13), and (15), RSMo.

James W. Coker, #2002027601, Rogersville, MO. Probation for two (2) years. As pharmacist-in-charge, repeat inspection violations. Multiple expired drugs in active stock. Section 338.055.2 (4), (5), (6), (13), and (15). RSMo.

Andrew D. Holt, #2014007091, Lees Summit, MO. Surrendered, and cannot reapply for five (5) years. Intern was terminated from employment for diverting controlled substances, including Alpraolam, Sertraline, Hydrocodone, Dextroamphetamine-Amphetamine, Tramadol, Carisoprodol, and Acetaminophen/Codeine. Created fraudulent prescriptions for himself and family members Section 338.055.2(5), (6), (13), (15) and (17), RSMo.

Charles D. Hudson, #040505, Webb City, MO. Probation for three (3) years. As pharmacist-in-charge, failed to provide adequate security for controlled substances, failed to maintain accurate controlled substance records. Section 338.055.2 (5), (6), and (15). RSMo.

Kenneth R. Mullins, Fayetteville, TN, Sixty (60) days suspension followed by three (3) years' probation. As Pharmacist-in-Charge, failed to follow company procedures. Dispensed medication without proper labeling. Section 338.055.2(6), (13), and (15), RSMo.

Skye L. Powers, Dixon, MO. Probation for three (3) years. As Pharmacist in Charge, returned prescriptions to stock without deleting the dispensings from the Pharmacy's records and reversing the claim. Section 338.055.2(4), (5), (6), (13), and (15), RSMo.

Wehmeier, Patrick, St. Charles, MO. Probation for five (5) years. Admitted to improper alcohol use. Section 338.055.2 (1), (5), and, (13), RSMo.

Zuchek, Sarah, House Springs, MO. As pharmacist, dispensed controlled substance prescriptions to herself without a prescription and/or dispensed a controlled substance to herself under a refill added without prescriber authorization Section 338.055.2(5), (6), (13), and (17), RSMo.

PHARMACIES:

CVS Pharmacy #5655, Liberty, MO. Probation for two (2) years Pharmacy had multiple controlled substance losses, failure to implement effective security controls. Section 338.055.2(5), (6), (13), and (15), RSMo.

CVS Pharmacy #8577, Kansas City, MO. Censure of license. The pharmacy failed to provide effective controls and procedures to guard against the theft of controlled substances. Section 338.055.2 (5), (6), (13), and (15) RSMo.

Heart of America Pharmacy, Grandview, MO. Probation for three (3) years. Allowed a technician to assist in processing of prescriptions prior to obtaining a Missouri permit. Participated in Class J activities without a Class J agreement and permit. Section 338.055.2(5), (6), (10), (12), and (12), RSMo.

Heartland Medical LLC. Lenexa, KS. Probation for three (3) years. Allowed a technician to assist in processing of prescriptions prior to obtaining a Missouri permit. Participated in Class J activities without a Class J agreement and permit. Section 338.055.2(5), (6), (10), (12), and (12), RSMo.

Hometown Pharmacy, Dixon, MO Probation for three (3) years. Returned prescriptions to stock without deleting the dispensings from the Pharmacy's records and reversing the claims. Section 338.055.2(4), (5), (6), (13), and (15), RSMo.

Medical Center Pharmacy. Doniphan, MO. Voluntary Surrender. Failed to timely dispense medication, failed to maintain accurate prescription and pharmacy records, failed to provide accurate prescription information, improper partial fills of Schedule II controlled substance prescriptions. Section 338.055.2 (5), (6), (13), and (15), RSMo.

Midwest Supply Chain, #2017043278, Shawnee Mission, KS. Probation for two (2) years. Failed to renew the previous drug distributor license; continued shipping legend drugs into Missouri for approximately 30 days. Section 338.055.2 (6) RSMo.

Rogersville Pharmacy, Rogersville, MO. Probation for two (2) years. Repeat inspection violations. Multiple expired drugs in active stock. Section 338.055.2 (4), (5), (6), (13), and (15). RSMo.

FDA REQUIRES LABELING UPDATE ON OPIOID-CONTAINING COUGH AND COLD MEDICINES

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.

LATEST NDTA SHOWS OPIOIDS POSE SIGNIFICANT IMPACT TO PUBLIC HEALTH

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the 2017 National Drug Threat Assessment (NDTA) report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the 2017 NDTA. To access the 2017 NDTA, visit www.dea.gov/divisions/hq/2017/hq102317.shtml.

FDA RECOGNIZES EIGHT EUROPEAN DRUG REGULATORY AUTHORITIES CAPABLE OF CONDUCTING INSPECTIONS

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.

INCORRECT USE OF INSULIN PENS AT HOME CAN CAUSE SEVERE HYPERGLYCEMIA

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of needle covers be explained to patients

who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at www.nccmerp.org/sites/default/files/nan-20171012.pdf.

FDA ADVISES ON OPIOID ADDICTION MEDICATIONS AND BENZODIAZEPINES

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found at www.fda.gov/Drugs/DrugSafety/ucm575307.htm.

ONLY ABOUT 3% OF PHARMACIES AND OTHER ENTITIES VOLUNTARILY MAINTAIN A PRESCRIPTION DRUG DISPOSAL BIN, GAO REPORTS

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs, is located on the GAO website at www.gao.gov/products/GAO-18-25.

ONE IN FIVE DRIVERS USES A PRESCRIPTION DRUG THAT CAN IMPAIR DRIVING DESPITE RECEIVING WARNINGS

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the Journal of Studies on Alcohol and Drugs on October 31, 2017, and can be found at https://doi.org/10.15288/jsad.2017.78.805.

PTCB CPHT PROGRAM EARNS ACCREDITATION FROM THE AMERICAN NATIONAL STANDARDS INSTITUTE

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of www.ptcb.org.